

REMARKS

In the Office Action dated September 13, 2007, claims 1, 2, 5, 6, 13, 14, 17, 18, 25, 28, 29, 32 and 33 were rejected under 35 U.S.C. §102(b) as being anticipated by Renirie et al. Claims 13, 15 and 30 were rejected under 35 U.S.C. §1039a) as being unpatentable over Renirie et al. Claims 4, 7-9, 16, 19-21, 26, 31, and 34-36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Renirie et al. in view of Obel et al. Claims 10, 22 and 37 were rejected under 35 U.S.C. §103(a) as being unpatentable over Renirie et al. in view of Hill et al. Claims 11, 22, 23, 24, 38 and 39 were rejected under 35 U.S.C. §103(a) as being unpatentable over Renirie et al. in view of Jensen et al.

Applicant notes with appreciation the telephone interview courteously afforded the undersigned representative of the Applicant on December 17, 2007, wherein the above claim amendments were discussed, as were Applicant's arguments in support of patentability of the amended claims. Those arguments are summarized below.

In addition to editorial amendments, independent claim 1 has been amended to bring the subject matter of claims 2 and 4 therein, independent claim 13 has been amended to bring the subject matter of claims 14 and 16 therein, and independent claim 28 has been amended to bring the subject matter of claims 29 and 31 therein. In view of the inclusion of the subject matter of claims 4, 16 and 31 in the respective independent claims 1, 13 and 28, the only relevant rejection that must now be addressed is the rejection under 35 U.S.C. §103(a) based on Renirie et al. in view of Obel et al. This rejection is respectfully traversed for the following reasons.

The Renirie et al. reference is concerned with a system and method for monitoring blood constituents that are related to diabetes, and more specifically for

determining a measure of a blood constituent such as insulin or glucose. For this purpose, ECG signals are obtained and monitored, and a processor correlates selected parameters of the ECG signal with blood insulin or blood glucose. The system provides an output that indicates a need for insulin or glucose, or can be used to automatically control an insulin injection.

The Renirie et al. reference does not disclose sensing of blood oxygen as the aforementioned blood constituent, and there is no indication in the Renirie et al. reference that sensing of blood oxygen would have any meaningful correlation with the intended purpose of the Renirie et al. reference, namely monitoring glucose or insulin in the blood.

The Examiner relied on the Obel et al. reference as disclosing sensing of blood oxygen, and identifying and using the first and second values as set forth in original claims 4, 16 and 21.

The Obel et al. reference concerns a method and apparatus for stimulating sinus nerves in order to prevent or interrupt myocardial ischemia. For this purpose, the Obel et al. reference first detects ischemia, and one of the ways disclosed in Obel et al. for doing so is to monitor oxygen saturation detected from a sensor located in the heart, preferably in the coronary sinus.

As the most fundamental argument for traversing the above rejection, Applicant respectfully submits that there is no obvious point of intersection between the disclosure of the Renirie et al. reference, which is for the purpose of monitoring insulin and blood glucose, and the method and apparatus disclosed in Obel et al., which is for monitoring and reacting to ischemia. The purpose of the Renirie et al. reference is to either emit a displayable signal, or a control signal, that either

indicates a glucose or insulin level, or automatically initiates insulin administration. Each of the independent claims of the present application, by contrast, requires that the aforementioned occurrence of the first and second values of blood oxygen level result in the control circuit emitting an output signal indicative of the functioning of the heart dependent on a relation between the first value and the second value. Regardless of the teachings of the Obel et al. reference, Applicant submits that modifying the Renirie et al. reference to provide the type of output set forth in the independent claims of the present application, instead of an output relating to or controlling glucose or insulin, would not only be a substantial redesign of the Renirie et al. reference, rather than an obvious modification thereof, but also would destroy the intended operation of the Renirie et al. reference if the signal relating to cardiac functioning replaced the glucose/insulin-related signal disclosed in Renirie et al. If a signal relating to cardiac functioning were emitted in Renirie et al. in addition to the insulin/glucose- related signal, it is not apparent what additional information this would provide to a user of the Renirie et al. method or apparatus.

More importantly, however, even in the Obel et al. reference there is no specific identification of a blood oxygen level in the diastolic phase of a heart cycle (or at least a portion thereof) and in the systolic phase of the same heart cycle (or a portion thereof), with these respective blood oxygen levels being actually identified as having occurred in those specific portions of the same heart cycle. In the Obel et al. reference, as in many other references, blood oxygen is continuously monitored, and therefore it is true that there will be some value of the blood oxygen level that happens to have been measured or detected during the diastolic phase, and some value of the blood oxygen level that happens to have been measured or detected in

the systolic phase. In the Obel et al. reference, however, even though these two blood oxygen levels may be present, there is no identification of a particular level that was obtained in the diastolic phase and another particular level that was obtained in the systolic phase. Therefore, in Obel et al. reference there is not, and cannot be, any identification of a relationship between these two blood oxygen levels that were measured at the times (phases) specifically required in the independent claims of the present application. In accordance with the present invention, it is not sufficient to simply arbitrarily select any two blood oxygen level values, which were respectively obtained at arbitrarily different points in time. It is necessary to know in advance *when* particular blood oxygen levels were being measured in the diastolic phase, and *when* particular blood oxygen levels were being measured in the systolic phase, in order to be able to identify, and then make use of, the aforementioned relationship. If there is simply a continuous stream of blood oxygen levels being measured, as in the Obel et al. reference, it will necessarily be the case that some were measured in the diastolic phase and some were measured in the systolic phase, but there is no information as to which measurements were made in which phase, and therefore it is not possible to identify the relationships that are identified in the independent claims of the present application, and the more specific relationships that are identified in a number of the dependent claims.

Therefore, even if the Renirie et al. reference were modified in accordance with the teachings of Obel et al., the subject matter of amended independent claims 1, 13 and 28 still would not result.

In the telephone interview, the Examiner proposed the possibility of “flipping” the rejection, so as to be Obel et al. modified in accordance with Renirie et al., rather

than Renirie et al. modified in accordance with Obel et al. Applicant submits that the above discussion makes clear that even if such a revised rejection were contemplated, the above arguments would still represent a relevant traversal of such a revised rejection. Moreover, in such a revised rejection, Applicant would be unable to ascertain any reason why a person of ordinary skill in the field of monitoring and detecting ischemia would seek guidance in a reference such as Renirie et al., concerned with monitoring glucose and insulin. Applicant respectfully submits that the Examiner has relied on the Renirie et al. reference only because it happens to make use of an ECG signal in the context of insulin/glucose monitoring. Simply because the Renirie et al. reference makes use of such an ECG signal, however, does not “convert” that reference into a reference having utility for making conclusions as to cardiac functioning. In fact, a person suffering from some type of cardiac disease or disability, whose ECG therefore would have significant deviations from a healthy ECG, would most likely distort the conclusions regarding insulin/glucose monitoring that are intended to be made from the ECG in the Renirie et al. reference. There does not appear to be any screening in the Renirie et al. reference to determine whether the ECG that is used for glucose/insulin monitoring is, in fact, a “healthy” ECG at least as far as cardiac health. The Renirie et al. reference simply accepts whatever ECG happens to be incoming from the patient, but there is no effort whatsoever to assess the cardiac functioning that is associated with the ECG signal in Renirie et al., and therefore there is no need to generate any signal that is indicative of cardiac functioning, as is required in each of the independent claims of the present application.

The remaining dependent claims add further structure or method steps to the independent claims, and are therefore patentable over the teachings of the further secondary references relied upon by the Examiner, for the same reasons discussed above in connection with the independent claims.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the present application is respectfully requested.

Since this Amendment only involves combining already-pending dependent claims with already-pending independent claims, and makes other minor editorial changes, this Amendment does not raise a "new issue" requiring further searching or consideration, and is therefore properly enterable at this stage of prosecution, after the Final Rejection. Moreover, in the aforementioned telephone interview, it was agreed that this Amendment would either place the application in condition for allowance, or would result in withdrawal of the Final Rejection and reopening of prosecution. Therefore entry of the present Amendment is respectfully requested.

The Commissioner is hereby authorized to charge any additional fees which may be required, or to credit any overpayment to account No. 501519.

Submitted by,

 (Reg. 28,982)

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